REMARKS

Claims 22-27, 41-42, 46-48, 50-56, 58, and 76-77 are pending. All claims were rejected in the final Office action mailed on June 9, 2003. On August 8, 2003, Applicants filed an amendment after final. An Advisory Action was mailed on September 5, 2003; and a Supplemental Advisory Action was mailed on September 26, 2003, admitting the amendment after final.

35 CFR §103 REJECTION

All claims remain rejected under 35 U.S.C. §103(a) as being unpatentable over Oshlack et al., (U.S. Pat. No. 5,356,467). In the final Office Action, the Examiner stated that:

> Oshlack teaches controlled release coating composition comprising zein, water soluble plasticizer, and mixture of rate-controlling agents, including water soluble hydrophilic polymers and modified starch (columns 4-5, and 7-9). ...The Examiner notes that the reference briefly mentions the combination of hydrophobic acrylic polymer as a pore-former, with no further indication or explanation as to its function. However, Oshlack teaches the advantageous results in obtaining a predetermined controlled release rate, or a selected desire release rate by adding a rate-controlling agent, erosion promoting agent, and release modifying passageways forming (column 4, lines 64 through column 5, lines 1-13). Thus it is the position of the examiner that it would have been obvious for one of ordinary skill in this art to, by routine experimentation determine a suitable amount of water-soluble rate-controlling agent, erosion promoting agent, or pore-forming agent to obtain a desirable release/dissolution rate.
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> The examiner notes that the reference teaches the use of hydrophobic acrylic polymer in certain preferred embodiments. However, applicant has not provided any comparative data showing that the present of the hydrophobic acrylic polymer would have a detrimental effect upon the desirability to obtain a useful coating composition. Hence, it would have been obvious for one of ordinary skill in the art to, by routine experimentation modify Oshlack's coating composition with the expectation of at least similar result, because Oshlack recognizes the properties of modified starch and cellul9se in coating composition useful for the same purpose desired by the applicant, e.g., coating composition for cleansing agent, therapeutic active agent, fertilizing agent, or disinfection agent.

With respect to Applicants' arguments, the Examiner stated,

> "In response to applicant's argument that the reference does not show certain feature of applicant's invention, it is noted that the feature upon which applicant relies (i.e., rapidly dissolve coating) is not recited in the rejected claims....Applicant claims and specification do not disclose, mention, or require the invention to be a rapid dissolve coating; nor applicant claims exclude the coating to be a "control coating". ...Applicant's claims do not exclude the coating from "controlled release", "sustained release", or "delayed release". The time release being argued in page 3 or applicant's remarks is irrelevant with respect to the scope of the claims. The language "a coating" permits any type of coatings, including the control coating disclosed by Oshlack." (emphasis added).
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> "...applicant has not provide data showing detrimental effect in the present of the present of the water-insoluble polymer in such a small amount 0.1% (column 3, line 56). ...applicant's claim language does not exclude the "controlled release" coating taught by Oshlack, therefore, it was suggested that applicant provides data showing detrimental effect in the use of hydrophobic acrylic polymer in an amount of 0.1%."
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> "The use of the transitional phrase "consisting essentially of" in applicant's generic claim 22 does not exclude the use of a small amount of hydrophobic polymer taught by Oshlack, because the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials and those that do not materially affect the basic and novel characteristic of the claim invention."
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> "The Declaration under 37 CFR 1.132 filed 04/12/03 has been fully considered, but is insufficient to overcome the rejection...because it does not provide a side by side comparison of the claimed invention and those of Oshlack to support the statement "adding hydrophobic acrylic polymer would result in loss of the rapid release". There was no data or experiment in the Declaration showing the coating containing 0.1% hydrophobic acrylic polymer in combination of water-soluble rate-controlling agent, erosion promoting agent, or pore-former that would result in loss of the rapid release. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness."

In addition to Applicants' arguments submitted on August 8, 2003, Applicants wish to point out that the Examiner's insistence on comparative results with 1% zein, a

water-insoluble material from the seeds of Indian corn, are misplaced. Oshlack et al. does not teach a coating of 0.1% zein at Col. 3, line 56, but rather teaches in the language cited by the Examiner "an aqueous dispersion of zein, the aqueous dispersion comprising from about 0.1 to about 10% zein".

The aqueous dispersion of zein is not the coating taught by Oshlack et al., but rather constitutes a solution that is used to form a coating. This coating solution of zein is about 60-90% organic solvent, which evaporates when coated onto the particle so that the actual amount of zein in the coating of Oshlack et al. is between 3-15% w/w. Please see the Examples. The Oshlack et al. teachings regarding coatings further state that, when pore-formers are uses, the amount of pore former by weight relative to the combined weight of hydrophobic acrylic polymer and pore-former is from about 0.1% to about 80%. Column 9, lines 62-66. Therefore, the pore former, the soluble element of the Oshlack et al. coating, does not exceed 80% of the coating which also may include a plasticizer in the amount of 20% to 40%, based upon the zein.

There is no teaching in Oshlack et al. of a 0.1% zein coating and Applicants are under no duty to provide comparative results using 0.1% zein or another hydrophobic acrylic polymer.

The error in the Examiner's reasoning is exemplified by the underlined language on page 3 of the Supplemental Office Action, specifically, "nor applicant claims exclude the coating to be a control coating". The Examiner must be looking only at the preamble of Applicants' claim 22 and ignoring the elements of the claim that define the "coating". Those elements recite starch with specific, enumerated modifications to improve solubility, a plasticizer, and a modified cellulose, wherein the coating is water soluble and does not contain a water insoluble polymer. Clearly the claim when read as a whole cannot apply to "any type of coatings" when the preamble is read in light of the recited elements of the claim, which elements define the coating. The clear meaning of the elements of the claim teach away from "controlled release" or "time release" and Applicants contend that such language is not necessary to distinguish over the reference in the elements themselves preclude "controlled" or "time" release. Claim 22 recites a limitation that the coating does not contain water insoluble polymer and does include a starch with recited modifications that improve solubility. Claim 76 recites a soluble coating comprising a modified starch dispersible in cold water, ...a plasticizer dispersible in cold water; and a modified cellulose dispersible at a temperature about 60

C. Without a water insoluble component, the coating is not a "controlled" or "time" release coating. Applicants' modified starch and modified cellulose components are water soluble and are not performing as "pore-formers" as taught by Oshlack et al. because Applicants' soluble coatings do not contain a water-insoluble component in which "pores" need to be formed. The Examiner is impermissibly ignoring the elements of the claim and the clear recognized meaning of terms within the claim.

Applicants respectfully request early examination and allowance of the claims.

Respectfully submitted,

Date: 11/4/03

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